UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, Plaintiff, v. MED PREP CONSULTING, INC., a corporation, and GERALD R. TIGHE, an individual, Defendants.	No. 13-3856 (PGS) CONSENT DECREE OF PERMANENT INJUNCTION

The United States of America, plaintiff, by its undersigned attorneys, having filed its complaint for injunctive relief against defendants, Med Prep Consulting, Inc., ("Med Prep"), a corporation, and Gerald R. Tighe, an individual (collectively, "Defendants"), and Defendants, without admitting or denying the allegations of the Complaint having appeared and having consented to the entry of this Consent Decree of Permanent Injunction (the "Decree"), without contest and before any testimony has been taken, and the United States of America, having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and over all parties to this action under 28 U.S.C. § 1345 and 21 U.S.C. § 332 and its inherent equitable authority.

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301-399d (the "Act").

3. A. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(d), by introducing and causing to be introduced, and delivering and causing to be

delivered for introduction, into interstate commerce, new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval;

B. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are adulterated within the meaning of 21 U.S.C. § 351(a)(1), in that they consist in whole or in part of a filthy, putrid, or decomposed substance;

C. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A), in that the drugs have been prepared, packed, and/or held under insanitary conditions whereby they may have been rendered injurious to health;

D. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, or the facilities or controls used for, the manufacture, processing, packing, and/or holding of drugs do not comply with current good manufacturing practice to assure that they meet the requirements of the Act as to their safety and that they have the identity and strength, and meet the quality and purity characteristics, which they purport or are represented to possess;

E. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are misbranded within the meaning of 21 U.S.C. § 352(j), in that they are

dangerous to health when used in a dosage or manner; or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; and

F. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of drug to become adulterated within the meaning of 21 U.S.C. §§ 351(a)(1), 351(a)(2)(A), and/or 351(a)(2)(B) and/or to become misbranded within the meaning of 21 U.S.C. § 352(j) while the drugs are held for sale after shipment of one or more of their components in interstate commerce.

4. For purposes of this Decree, the following definitions shall apply:

A. "Manufacturing" shall include compounding, repackaging, manufacturing, processing, packing, repacking, and labeling.

B. "Manufacture" shall include compound, repackage, manufacture, process, pack, repack, and label.

C. "Med Prep Facilities" shall refer to the facility located at 1540 West Park Avenue, Suite 5, Tinton Falls, New Jersey and any other location (including any additional location(s)) at which Defendants manufacture articles of drug within the meaning of 21 U.S.C. § 321(g)(1);

D. "Drug" shall have the meaning given in 21 U.S.C. § 321(g)(1);

E. "Sterile drug" shall refer to any drug within the meaning of 21 U.S.C. § 321(g)(1) that is labeled as sterile or otherwise purports to be sterile, and to any drug that, by nature of its intended use or method of administration, is expected to be sterile;

F. "CGMP" shall refer to current good manufacturing practice as defined in 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210 and 211; and

G. "Days" shall refer to calendar days unless otherwise stated.

5. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree

by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly manufacturing, holding and/or distributing any drugs at or from the Med Prep Facilities, unless and until the following conditions are met:

A. Defendants have in effect for each and every new drug an approval pursuant to 21 U.S.C. § 355(a), or an exemption from approval;

B. Defendants' methods, facilities, and controls used to manufacture, hold, and/or distribute drugs are established, operated, and administered in conformity with CGMP;

C. Defendants (in the manner and as described in 21 U.S.C. § 510) register with FDA all Med Prep Facilities, and file with FDA a list of all drugs manufactured at the Med Prep Facilities;

D. Defendants retain, at Defendants' expense, an independent person or persons (the "CGMP Expert"), who: (i) is without any personal or financial ties (other than a retention agreement to satisfy the requirements of this provision, or retention agreements entered into prior to the entry of this Decree) to Defendants or their families; and (ii) by reason of background, training, education, or experience, is qualified to inspect the Med Prep Facilities to determine whether the methods, facilities, and controls are operated and administered in conformity with CGMP and to recommend corrective actions. Defendants shall notify the United States Food and Drug Administration ("FDA") in writing of the identity and qualifications of any current or future CGMP Expert within ten (10) days after entry of this Decree or of retaining any such CGMP Expert, whichever comes first;

E. Defendants shall submit a protocol that identifies the work plan for the CGMP expert and the methodology that shall be used by the CGMP Expert (the "work plan") to: (i) conduct the inspection as set forth in paragraphs 5.F-G; (ii) ensure that Defendants' corrective actions are implemented; and (iii) ensure that the manufacture, holding, and distribution of drugs will be continuously administered in conformity with CGMP. Defendants shall first obtain

FDA's written approval of the work plan prior to the CGMP Expert performing his or her inspection as set forth in paragraphs 5.F-G;

F. The CGMP Expert reviews the Forms FDA-483 issued to Defendants on April 3, 2013, and performs a comprehensive inspection of the Med Prep Facilities and the methods and controls used to manufacture, hold, and distribute drugs to determine whether such facilities, methods, and controls are, at a minimum, in conformity with CGMP. The CGMP Expert shall, at a minimum:

(1) Evaluate whether Defendants thoroughly review any unexplained discrepancy and the failure of any batch or any of its components to meet any of its specifications whether or not the batch has already been distributed. The CGMP Expert's evaluation shall include, but not be limited to, determining whether Defendants identify the causes of the discrepancy and implement adequate corrective actions;

(2) Determine whether Defendants' laboratory controls, including but not limited to controls for Defendants' contract testing laboratory(-ies), include the establishment of scientifically sound and appropriate sampling plans and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity. Such controls shall include, but not be limited to, procedures for performing batch sterility and endotoxin testing;

(3) Determine whether Defendants have in place an adequate written testing program designed to assess the stability characteristics of drug products. The CGMP Expert's determination shall extend to a determination of whether an adequate number of Defendants' batches of each drug product are tested to determine an appropriate expiration date and to assure stability for all appropriate attributes and characteristics;

(4) Determine whether Defendants' reserve drug product samples are retained and stored under conditions consistent with product labeling, and are periodically examined with appropriate follow-up as needed;

(5) Evaluate whether equipment used in the manufacture or holding of Defendants' drug products is of appropriate design to facilitate operations for its intended use, cleaning, and maintenance;

(6) Determine whether Defendants have adequately designed the Med Prep Facilities to have adequate space for the orderly placement of equipment and materials to prevent mixups between different components, drug product containers, closures, labeling, in-process materials, or drug products and to prevent contamination. Such determination shall include, but not be limited to, the CGMP Expert's evaluation of whether Defendants' operations relating to the manufacture of beta-lactam antibiotics, including penicillin, are performed in facilities separate from those used for other drug products for human use;

(7) Determine whether Defendants' air handling systems for the manufacture of penicillin are completely separate from those for other drug products for human use;

(8) Evaluate whether the flow of components, drug product containers, closures, labeling, in-process materials, drug products through the building are adequately designed to prevent contamination. The CGMP Expert's evaluation shall include, but not be limited to, the following:

a. Evaluating the flow of personnel, material flow, room segregation, process separation, and the impact from and adequacy of HVAC, air pressurization and unidirectional airflow; and

b. Evaluating whether the adjacent cleanroom, the aseptic processing cleanroom, and barrier protection of ISO 5 Zone, are suitably designed to and provide for separation of individual process and functions, and robustly prevent hazards to the exposed sterile product;

(9) Evaluate whether Defendants' standard operating procedures include adequate requirements regarding the use of clean clothing appropriate for the operations performed to protect their drug products from contamination, including but not limited to sterile gowning components;

(10) Evaluate whether Defendants' written procedures include maintenance, cleaning, and disinfection schedules, described in sufficient detail, including the methods, equipment, and materials used, instructions for protection of clean equipment and utensils from contamination, and parameters relevant to the operation;

(11) Evaluate whether Defendants' cleaning and disinfection solutions and procedures are validated and shown to be effective for their intended use;

(12) Determine whether Defendants' master production and control records contain complete manufacturing and control instructions and sampling and testing procedures;

(13) Determine whether Defendants' batch records include complete information relating to the production and control of each batch;

(14) Determine whether Defendants establish and follow written procedures designed to prevent microbiological contamination of drug products purporting to be sterile, including, but not limited to, operational procedures, procedures for dynamic smoke studies, and procedures for the conduct of appropriate ongoing media fill simulations;

(15) Determine whether Defendants' written procedures are drafted, reviewed, and approved by the appropriate organizational units;

(16) Evaluate whether Defendants have established and implemented a comprehensive written Quality Assurance ("QA")/Quality Control ("QC") program that is adequate to ensure continuous compliance with the Act, its implementing regulations, and this Decree; and

(17) Evaluate whether Defendants' facility has separate or defined areas or other such control systems for the firm's operations as are necessary to prevent contamination or mixups during the course of aseptic processing. The CGMP Expert's evaluation shall include, but not be limited to, determining whether Defendants have adequately designed and implemented a routine environmental monitoring program that monitors batches under dynamic conditions. This environmental monitoring program shall include evaluation of actual operations and assessment of personnel, surfaces, and air quality, and shall identify and address any results beyond appropriate pre-established limits and any adverse trends.

G. The CGMP Expert certifies in writing to FDA and the Defendants that:

(1) The CGMP Expert has inspected Defendants' facilities, methods, and controls;

(2) All deviations from CGMP brought to Defendants' attention by FDA, the CGMP Expert, or any other source have been corrected; and

(3) Such facilities, methods, processes, and controls are in compliance with the requirements of CGMP. As part of this certification, the CGMP Expert shall include a detailed and complete report of the results of the CGMP Expert's inspections conducted under paragraph 5.F;

H. Defendants establish and maintain a system to report to FDA all serious, unexpected adverse drug experiences (in the manner and as defined in 21 C.F.R. § 314.80) associated, directly or indirectly, with any and all of Defendants' drug products no later than fifteen (15) days after initial receipt of the information, via the MedWatch reporting system;

I. Defendants establish and maintain a system to submit to the FDA New Jersey District Office Field Alert Reports (in the manner and as described in 21 C.F.R. § 314.81(b)(1)) for all of Defendants' distributed drug products within three (3) working days from initial receipt of the information triggering the Field Alert Report;

J. Defendants report to FDA in writing the actions they have taken to:

(1) Correct the CGMP deviations brought to Defendants' attention by FDA, the CGMP Expert, or any other source;

(2) Ensure that the methods used in, and the facilities and controls used for, manufacturing, holding, and distributing drugs are operated and will be continuously administered and operated in conformity with CGMP;

K. If FDA, in its sole discretion, determines that inspection(s) is/are necessary, FDA representatives inspect the Med Prep Facilities to determine whether the requirements of this Decree have been met, and whether those facilities are otherwise operated in conformity with CGMP; and

L. Following any inspection(s) by FDA under subparagraph (K), FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs 5.A-.I.

6. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any act that:

A. Violates 21 U.S.C. § 331(d) by introducing and/or causing the introduction into interstate commerce, and/or delivering and/or causing the delivery for introduction into interstate commerce, any new drug that is neither approved under 21 U.S.C.

§ 355(a), nor exempt from approval;

B. Violates 21 U.S.C. § 331(a) by introducing and/or causing to be introduced, and/or delivering or causing to be delivered for introduction, into interstate commerce, any drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(1);

C. Violates 21 U.S.C. § 331(a) by introducing and/or causing to be introduced, and/or delivering or causing to be delivered for introduction, into interstate commerce, any drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A);

D. Violates 21 U.S.C. § 331(a) by introducing and/or causing to be introduced, and/or delivering or causing to be delivered for introduction, into interstate commerce, any drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

E. Violates 21 U.S.C. § 331(a) by introducing and/or causing to be introduced, and/or delivering or causing to be delivered for introduction, into interstate commerce, any drug that is misbranded within the meaning of 21 U.S.C. § 352(j); and/or

F. Violates 21 U.S.C. § 331(k) by causing any drug to become adulterated within the meaning of 21 U.S.C. §§ 351(a)(1), 351(a)(2)(A) and/or 351(a)(2)(B), or misbranded within the meaning of 21 U.S.C. § 352(j) while such drug is held for sale after shipment of one or more of its components in interstate commerce.

7. Except as provided in this paragraph, within fifteen (15) days after entry of this Decree, Defendants shall, under FDA supervision, destroy all drug products and in process materials in Defendants' possession, custody, and/or control that are the subject of recalls announced by Med Prep in March 2013. With respect to any additional recalled drug products that subsequently come into the Defendants' possession, custody, or control, the Defendants shall quarantine any such products, promptly notify FDA of their receipt, and destroy any such products, under FDA's supervision, no later than thirty (30) days after their receipt. Recalled drug products that are the subject of pending or threatened litigation,

however, may be preserved for evidentiary purposes only, for so long as that need exists, but shall be destroyed, under FDA's supervision when that need no longer exists. Within thirty (30) days after receipt of a reasonable detailed bill of costs, Defendants shall reimburse FDA for the supervisory tasks associated with any destruction under this paragraph at the rates set forth in paragraph 12 of this Decree. Defendants shall not dispose of any drugs in a manner contrary to any federal, state, or local laws, including but not limited to, the National Environmental Policy Act of 1969.

8. After Defendants have complied with paragraph 5 and have received written notification from FDA under paragraph 5.L, Defendants shall retain an independent person who meets the criteria described in paragraph 5.D (the "Auditor"), and who may, if Defendants choose, be the same person(s) retained as the CGMP Expert in paragraph 5.D, to conduct audit inspections of their manufacturing and quality operations at the Med Prep Facilities. Defendants shall notify FDA in writing as to the identity and qualifications of the Auditor as soon as they retain such Auditor. After Defendants receive written notification from FDA under paragraph 5.L, audit inspections under this paragraph shall commence no less frequently than once every three (3) months for a period of one (1) year, and once every six (6) months thereafter for an additional four (4) year period after Defendants receive written notification under paragraph 5.L.

A. At the conclusion of each of the audit inspections described in paragraph 8, the Auditor shall prepare a written audit report ("Audit Report") analyzing whether Defendants are in compliance with CGMP, and identifying all deviations ("audit report observations"). Beginning with the second Audit Report, the Auditor shall also assess the adequacy of any corrective actions taken by Defendants to correct all previous audit report observations, and include this information in the Audit Report(s). The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service no later than fifteen (15) business days after the date each audit inspection is completed.

In addition, Defendants shall maintain the Audit Reports in a separate file at the Med Prep facility to which the report pertains and shall promptly make the Audit Reports available to FDA upon request; and

B. If an Audit Report contains any audit report observations, Defendants shall, within thirty (30) days after receipt of the Audit Report, correct those deviations at all applicable facilities, unless FDA notifies Defendants in writing that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of the deviations will take longer than thirty (30) days, Defendants shall, within ten (10) days after receipt of the audit report, propose a schedule for completing corrections. FDA shall, as it deems appropriate, review and approve the proposed schedule in writing prior to implementation. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) days after Defendants' receipt of an Audit Report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the audit report observations. Within five (5) business days after beginning that review, the Auditor shall report in writing to FDA whether each of the audit report observations has been fully corrected and, if not, which audit report observations remain uncorrected.

9. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, analyses of samples, a report or data prepared or submitted by Defendants, the CGMP Expert(s), or the Auditor(s), or any other information, that Defendants have failed to comply with the provisions of this Decree, have violated the Act, or that additional corrective actions are necessary to achieve compliance with the Act and/or this Decree with respect to any of Med Prep's products or any Med Prep Facility, FDA may, as and when it deems necessary,

notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action at any or all Med Prep Facility(ies), including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease all manufacturing, holding, and/or distributing of any and all drug(s);

B. Recall specified drugs manufactured, held, and/or distributed by Defendants. The recall(s) shall be initiated within five (5) days after receiving notice from FDA that a recall is necessary. Defendants shall, under FDA supervision, destroy all finished and/or in-process drugs and components that are in Defendants' possession, custody, or control, for which a recall was initiated. Defendants shall bear the costs of such recall(s), including the costs of destruction and the costs of FDA's supervision at the rates specified in paragraph 12. Defendants shall be responsible for ensuring that the destruction is carried out in a manner that complies with all applicable federal and state environmental laws, and any other applicable federal or state law;

C. Submit additional reports or information to FDA;

D. Repeat, revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;

E. Issue a safety alert with respect to a drug manufactured, held, or distributed by Defendants; and/or

F. Take any other corrective action(s) as FDA, in its discretion, deems necessary to protect the public health or bring Defendants into compliance with this Decree or the Act.

This remedy shall be separate and apart from, and in addition to, any other remedy available to the United States under this Decree or under the law.

10. Upon receipt of any order issued by FDA pursuant to paragraph 9, the following procedures shall apply:

A. Unless a different time frame is specified by FDA in its order, Defendants shall, within ten (10) business days after receiving such order, notify FDA in writing that: (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants may propose specific alternative actions and specific time frames for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it will explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and if they so choose, bring the matter before this Court on an expedited basis. Defendants shall continue to diligently implement FDA's order, unless the Court sets aside, stays, reverses, vacates, or modifies FDA's order. Any review of FDA's decision under this paragraph shall be made in accordance with the terms set forth in paragraph 18 of this Decree.

D. The process and procedures set forth in paragraph 10.A.-C. shall not apply to any order issued under paragraph 9 if such order states that, in FDA's judgment, the matter raises significant public health concerns. In such case, Defendants shall immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition this Court for relief while they implement the order.

11. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of the Med Prep Facilities, collect samples, and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted access to the Med Prep Facilities including, but not limited to, all buildings, equipment, in-process or unfinished and finished materials and products, containers, labeling, and other promotional material therein; to take photographs and make video recordings; to take samples – without charge to FDA – of Defendants' finished and unfinished materials and products, containers and packaging material therein, labeling, and other promotional material; and to examine and copy all records relating to the receipt, manufacturing, holding, and distribution of any and all drugs and their components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

12. Defendants shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree, at the standard rates prevailing at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $87.57 per hour and fraction thereof per representative for inspection work; $104.96 per hour or fraction thereof per representative for analytical or review work; $0.565 per mile for travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

13. Within ten (10) days after entry of this Decree, Defendants shall post a copy of this Decree on a bulletin board in the employee common areas at each and every Med Prep Facility. Defendants shall ensure that the Decree remains posted at every Med Prep Facility for as long as the Decree remains in effect.

14. Within ten (10) days after the entry of this Decree, Defendants shall provide a copy of this Decree, by personal service or registered mail, to each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (collectively referred to as "Associated Persons"). Within thirty (30) days of the date of entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of this paragraph and identifying the names, addresses, and positions of all persons who have received a copy of this Decree.

15. In the event that any of the Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants immediately shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Within thirty (30) days of each time any of the Defendants becomes associated with any such additional Associated Person(s), Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts. Within ten (10) days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

16. Defendants shall notify FDA at least fifteen (15) days before any change in ownership, character, or name of their businesses, including incorporation, reorganization,

bankruptcy, assignment, or sale resulting in the emergence of a successor business or corporation, the creation or dissolution of subsidiaries, or any other change in the corporate structure or identity of Med Prep, or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any potential successor or assign at least fifteen (15) days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) days prior to such assignment or change in ownership.

17. If Defendants fail to comply with any of the provisions of this Decree with respect to any of Med Prep's products or any Med Prep Facility, including any time frame imposed by this Decree, then, on motion of the United States in this proceeding, Defendants shall pay to the United States of America: fifteen thousand dollars ($15,000) in liquidated damages for each day such violation continues; an additional sum of fifteen thousand dollars ($15,000) in liquidated damages for each violation of the Act, its implementing regulations, and/or this Decree; and further additional sum equal to the retail value of drug products that have been distributed in violation of this Decree. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

18. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time of the decision. No discovery shall be taken by either party.

19. Should the United States of America bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants shall pay all attorneys' fees and costs, travel

expenses incurred by attorneys and witnesses, expert witness fees, investigational and analytical expenses, and court costs incurred by Plaintiff in bringing such an action.

20. All notifications, certifications, reports, correspondence, and other communications to FDA required by the terms of this Decree shall be marked "Consent Decree Correspondence" and shall be addressed to the Director, FDA New Jersey District Office, 10 Waterview Blvd, 3rd Floor, Parsippany, NJ 07054.

21. If any deadline in this Decree falls on a weekend or holiday, the deadline is continued to the next business day.

22. This Court retains jurisdiction of this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

IT IS SO ORDERED, this 27 day of June, 2013.

UNITED STATES DISTRICT JUDGE

The undersigned hereby consent to the entry of the foregoing Decree.

FOR DEFENDANTS

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Individually and on behalf of
MED PREP CONSULTING, INC., as its
President and Owner

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